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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,920	09/26/2001	Francis Barany	19603/3356 (CRF D-1595F)	1149

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EXAMINER	
PONNALURI, PADMASHRI	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 02/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/963,920	BARANY ET AL.	
	Examin r	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication app ars on th cover sheet with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *120-137* is/are pending in the application.

4a) Of the above claim(s) *126 and 129-135* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *120-125,127,128,136 and 137* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/26/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group XI, claims 120-137 in Paper No. 11072003 is acknowledged. NOTE that applicants state that group XI is elected with traverse, however the rest of claims (groups) were canceled, and no arguments why the groups are not distinct from each other are not presented, thus the election is considered as election without traverse.

2. Applicant's species election with traverse of: (1) glass as solid support; (2) slide as form of support; (3) carboxyl as functional group; (4) oligonucleotide having a nucleotide sequence complementary to SEQ ID NO: 2 as specific capture ligand, in Paper No. 11072003 is acknowledged. The traversal is on the ground(s) that all the species of the elected invention are closely related and require common areas of search and consideration. This is not found persuasive because the different species of the claimed invention are closely related as in applicant's response. For example the different groups of functional groups used in the instant claimed method would result in distinct products and require different process steps in obtaining the product (e.g., array). And further the non-patent or patent literature search for one species would not result in finding other species. Thus species election between the different functional groups is proper.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 126 (solid support is microtitre plate), 127 (linker comprises silane), 129-135 (functional group other the elected 'carboxyl') withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species election, there being no allowable

generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11072003.

Status of Claims

4. The preliminary amendment filed on 9/26/01 has been fully considered and entered into the application. Claims 1-119 and 138-147 have been canceled by the preliminary amendment filed on 9/26/01.

5. Claims 120-125, 128, 136-137 are currently being examined in this application.

6. The amendment filed on 11/7/03 amends the claim 120 include limitations 'wherein each oligonucleotide probe of the array differs from its adjacent oligonucleotide probe by at least 25 % of the nucleotides.'

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 120-125, 128, 136-137 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The instant claim recites an array of oligonucleotides.

The limitation 'wherein each oligonucleotide probe of the array differs from its adjacent

oligonucleotide probe by at least 25 % of the nucleotides' claimed in claim 120 has no clear support in the specification and the claims as originally filed. Applicants have stated that the support for the limitation is found in original claim 81. The original claim 81 which is dependent on claim 80, which depends on claim 1, recites 'the capture oligonucleotide differs from its adjacent capture oligonucleotide on the array by at least 25 % of the nucleotides.' The 'capture oligonucleotide' of claim 81 is not same as the instant claim oligonculeotide probe. In the instant claim oligonucleotide probe is distinct from the capture oligonucleotide of either claim 1 or claim 81. Thus the amendment to claim 120 has no clear support in the specification.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 120-125, 128 and 136-137 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 120 is indefinite by reciting 'at least some of the array positions' it is not clear what does applicants mean 'at least some', the metes and bounds of 'at least some' is not clear. Whether 50 % constitutes at least some or 90 % constitutes at least some positions. Applicants are requested to amend the claim.

Claim 120 is indefinite by reciting 'a linker or support suitable for coupling an oligonucleotide probe to the solid support...', it is not clear what does applicants mean by support suitable for coupling to the solid support. Does applicants mean the oligonucleotide is

coupled to the solid support by using a different support. Applicants are requested to amend the claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 120-125, 136-137 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,744,305 (FODOR et al).

The instant claim briefly recites an array of oligonucleotide probes on a solid support comprising: a solid support having an array of positions each suitable for attachment of an oligonucleotide probe; a linker or support suitable for coupling an oligonucleotide probe to the solid support attached to the solid support at each of the array positions; and an array of oligonucleotide probes on the solid support with at least some of the array positions being occupied by oligonucleotide probes having greater than sixteen nucleotides, wherein each oligonucleotide probe of the array differs from its adjacent oligonucleotide probe by at least 25 % of the nucleotides.

Fodor et al teach arrays of materials attached to a substrate. The reference claims are drawn to an array of oligonucleotides comprising: a plurality of different oligonucleotides

attached to the surface of solid support at different predetermined positions (e.g., see claim 1) reads on the instant claim array. The reference claim 2 recites each different oligonucleotide is from about 4 to about 20 nucleotides in length (refers to at least some of the oligonucleotides having greater than sixteen nucleotides. And claim 4 recites that oligonucleotides are at least 20 nucleotides in length. The reference claim 9 recites that the oligonucleotides are attached to the surface of the solid support through a linker group (refers to the linker of the instant claims). The reference claim 8 recites that the solid support is glass. Claim 7 of the reference recites that the predefined regions of the support is physically separated from each other. The reference in column 6 (lines 34-38) teaches that separate synthesis regions for different polymers with, for example wells, raised regions, etched trenches or the like (refers to the instant claim 125). The reference teaches the use of glass microscope slide as solid support (e.g., see column 8, line 49) (refers to instant claims 122-123). Claims 121 and 137 are considered as intended use. Thus the reference clearly anticipates the claimed invention.

13. Claims 120-124. 136-137 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,837,832 (CHEE et al).

Chee et al teach arrays of nucleic acid probes on biological chips. Chee et al methods for Making high density arrays of oligonucleotide probes on DNA chips, in which the probes have specific sequences and locations in the array to identify specific target nucleic acid (refers to array of positions and claim 121) (e.g., see column 1, lines 61-65). The reference teaches that the probes are arranged on the chip so that probes for a given position in the reference sequence are also adjacent to one another in the chip (e.g., see column 2). The reference teaches that the arrays

of many thousands of oligonucleotide probes are arranged on a glass slide or chip (e.g., see column 5, refers to instant claim 123). The reference teaches that are the arrays are synthesized directly on the support using VLSIPS technology. The reference teaches that the support is derivitized with functional groups such that the oligomers are attached to the substrate surface (refers to instant claim linker or support). The reference teaches that lengths ranging from 12 to 18 bases are preferred, although shorter and longer lengths can also be employed (refers to instant claim probes having greater than sixteen nucleotides) (e.g., see column 6, lines 4-7). The reference teaches individual probes, sets of probes and arrays of probe sets on chips, and gives an example of sequences (e.g., see column 10, lines 40-49). For example the reference sequences SEQ ID NO: 9 and SEQ ID NO: 10 differ by more than 25% nucleotides. And the reference teaches that sets of shorter probes derived from the 51 end of each probe and sets of longer probes made from this set by adding 5` end of each probe (refers to probes greater than 16 nucleotides of the instant claims). The reference teaches that methods for synthesizing large number of probe sets in a defined array in which the probes are arranged in the array by tiling method of the invention (refers to instant claim 122) (e.g., see column 12, lines 60-64). The reference clearly anticipates the claimed invention.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 120-125, 128, 137-138 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-153 of copending Application No. 10/272,152. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference method of identifying one or plurality of sequences differing in target nucleotide sequence requires or uses the instant claim array.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 120-125, 128, 136-137 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over allowed claims of copending Application No. 08/794,851. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference method of identifying one or

more plurality of sequences differing by one or more single base changes in a plurality of target nucleotide sequences uses the array of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 120-125, 128, 136-137 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-75 of U.S. Patent No. 6,506,594 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because to practice the reference method for identifying one or more plurality of sequences differing by one or more single base changes insertions, deletions, or translocations in a plurality of target nucleotide sequences requires the array of the instant claim.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Flex Schedule and can normally be reached From Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

Pp
18 February 2004